REMARKS

Claims 14, 17, 19, 20, 32-34, 36-38, 40-42 and 44-50 are pending in the application with entry of this Amendment. Claims 32-35, 40 and 41 are currently amended. New claims 44-50 are added. Claims 35 and 39 are canceled without prejudice. The amendments and new claims do not present new matter. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Rejections

Applicants acknowledge that the following rejections in prior Office Actions have been withdrawn:

A. Rejection of claims under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,309,909 to Gadsby ("Gadsby").

B. Rejection of claims under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,277,117 to Tetzlaff.

C. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Tetzlaff in view of U.S. Patent No. 6,162,220 to Nezhat.

D. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Gadsby in view of U.S. Patent No. 4,685,466 to Rau ("Rau")

E. Rejection of claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Gadsby in view of U.S. Patent No. 6,091,975 to Daddona ("Daddona")

II. Claims 14 and 32 Are Patentable Over Rau and Baker

Independent claims 32 and dependent claim 14 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Rau in view of U.S. Patent No. 6,228,082 to Baker *et al.* ("Baker"). Applicant respectfully traverses the rejection and respectfully submits that rejection is moot in view of the deficiencies of the cited references, individually and in combination, and the manner in which the Office Action misconstrues what is actually disclosed by certain references.

Rau fails to disclose "a tissue stimulation element having a diameter of about 0.5mm to 1.0mm and configured to emit stimulation energy that is applied to tissue, wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion" and that is

structured relative to a means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure "*without* the tissue stimulation element piercing the tissue" as recited in claim 32. As recited in claim 32, the means for securing the surgical apparatus to tissue engages tissue, and the stimulation element does not pierce the tissue.

It is alleged the "needle electrode having a pointed tip 1" is a "stimulation electrode" as recited in claim 32. Office Action (p. 2, referring to "pointed tip 1" and col. 4, lines 28-62 and Figs. 1-6). Col. 4, lines 28-62 describe a measuring sensor with a single electrode. Rau (col. 4, lines 29-30). The needle point 1 is embedded within a mounting 2. Rau (col. 4, lines 31-32). Rau explains that this needle point 1 is introduced through the physiological 'skin' barrier, and that the needle point 1 has as its essential part one or more short needle points which penetrate into the uppermost largely cast-off cell layers of the horny skin...Rau (Abstract) (emphasis added). Rau (col. 2, lines 42-44) (emphasis added). This is in contrast to pure surface electrodes that are merely brought in contact with the body surface. Rau (Abstract). Accordingly, Rau describes a configuration that is the opposite of the configuration recited in claim 32 since claim 32 specifically recites that the stimulation element does not pierce tissue and in this regard, is a "surface" electrode, which is specifically distinguished by Rau. Rau (Abstract) (distinguishing non-penetrating surface electrodes).

Rau also fails to disclose "means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure" and pressing the stimulation element against the single side of the tissue structure without the tissue stimulation element piercing the tissue as recited in claim 32. It is alleged that a suction cup 2 and vacuum line 4 described by Rau correspond to this claim element. Office Action (p. 2). However, the subject application does not refer to vacuum when discussing a means for securing a surgical apparatus to tissue and such that a tissue stimulation element associated therewith does not penetrate tissue.

Thus, the basis of the allegations regarding Rau are not clear, and Baker, which is cited for the limited purpose of allegedly disclosing certain dimensions, does not cure these deficiencies. Consequently, Rau and Baker, individually and even if somehow combined, fail to disclose each limitation of claim 32.

Further, Rau teaches away from claim 32 since Rau specifically explains that the needle 1 penetrates into horny cell layers of the skin and specifically differentiates electrodes that are "brought in contact with the body surface" such as a tissue stimulation element that is pressed against tissue without piercing the tissue.

Applicant respectfully submits that independent claim 32 is patentable over Rau and Baker, even is somehow combined. Dependent claim 14 depends from and incorporates the elements of independent claim 32 and, therefore, is also believed patentable over the cited references.

Accordingly, Applicant respectfully request that the rejection of claims 14 and 32 under 35 U.S.C. §103(a) be withdrawn.

III. Claims 17, 19, 20 and 33 Are Patentable Over Hess and Baker

Independent claims 33 and dependent claims 17, 19 and 20 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,144,890 to Hess ("Hess") in view of Baker. Applicant respectfully traverses the rejection and respectfully submits that the rejection is moot in view of the deficiencies of the cited references, individually and in combination, and the manner in which the Office Action misconstrues what is actually disclosed by certain references.

Hess fails to disclose "an anchor carrying the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue and to press the stimulation element against the tissue without the tissue stimulation element piercing the tissue" as recited in claim 33. It is alleged that components 21 and 37 described by Hess collectively form a "stimulation electrode" as recited in claim 33. Office Action (p. 3, citing col. 2, line 31 – col. 3, line 35). Hess describes these components as a "projecting electrode 21" and "a highly sharpened, multifaceted point, as indicated at 37" or a "tip 37." Hess (col. 2, lines 56-61) (emphasis added). Hess further explains that this highly sharpened point 37 is designed for

"pushing the tip 37 into the tissue ..." Hess (col. 2, lines 62-63) (emphasis added). In other words, this highly sharpened tip 37 pierces or penetrates the tissue. Hess describes a configuration that is the opposite of the configuration recited in claim 33. Further, given the particular sharpened tip structure that is described, Hess teaches away from a stimulation element that does not pierce tissue as recited in claim 33.

Otherwise, it is alleged that components 25, 27, 31 and 33 described by Hess collectively form a "anchor" as recited in claim 33. Office Action (p. 3, citing col. 2, line 31 – col. 3, line 35). However, as recited in claim 33, an "anchor" is configured to secure the surgical apparatus to tissue by piercing the tissue and, in addition, to press the stimulation element against the tissue without piercing the tissue. Hess describes these four components as a "'attaching members 25 and 27" and "fishhook-type barbs 31 and 33." Hess (col. 2, lines 43 and 54). Hess further explains that these attaching members 25, 27 and fishhook-type barbs 31, 33 are configured to permit the contact device to be "screwed in" to the cardiac muscle tissue during application of the device. Hess (col. 2, lines 49-55). Thus, these cited components also cannot be a "stimulation element" as recited in claim 33.

Baker does not cure these determinative deficiencies. Hess and Baker, individually and even if somehow combined, fail to disclose each limitation of claim 33, and Hess teaches away from claim 33 given that the alleged stimulation element (components 21 and 37) are specifically designed to pierce tissue. Applicant respectfully submits that independent claim 33 is patentable over Hess and Baker. Dependent claims 17, 19 and 20 depend from and incorporate the elements of independent claim 33 and, therefore, are also believed patentable over the cited references.

Further, with respect to dependent claims 19 and 20, Applicant notes that the Office Action includes remarks concerning independent claim 33 with respect to the device shown in Fig. 2 of Hess, but then refers to attachment member 42 (attachment members 41-44), which is part of a different device shown in Fig. 4. Comparing Figs. 2 and 4, the device shown in Fig. 4 does not include the alleged anchor components (25, 27, 31 and 33). Regardless, the device shown in Fig. 4 of Hess also includes a sharply pointed tip 37 for piercing tissue and, therefore, Fig. 4 of Hess also fails to disclose an anchor configured to secure a surgical apparatus by piercing tissue and also pressing a stimulation element against tissue without piercing tissue

since the sharpened tip 37 is specifically designed and used to pierce tissue. Fig. 4 of Hess also teaches away from Applicant's claims.

Accordingly, Applicant respectfully request that the rejection of claims 17, 19, 20 and 33 under 35 U.S.C. §103(a) be withdrawn.

IV. Claims 34-37, 40 and 42 Are Patentable Over Rau, Franchi and Daddona

Independent claim 34 and dependent claims 35-37, 40 and 42 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Rau in view of U.S. Patent No. 5,466,255 to Franchi ("Franchi") and Daddona. Applicant respectfully traverses the rejection and respectfully submits that rejection is moot in view of the deficiencies of the cited references, individually and in combination, and the manner in which the Office Action misconstrues what is actually disclosed in certain references.

Rau fails to disclose "a first tissue stimulation element and a second tissue stimulation elements that are configured to emit stimulation energy that is applied to tissue" as recited in claim 34. It is alleged that Rau discloses "a tissue stimulation" element, *i.e.*, it is alleged that Rau discloses one stimulation element, but the Office Action is silent as to how Rau discloses a second stimulation element as recited in claim 34. Nevertheless, Rau cannot support the rejection since Rau describes a single needle point 1. Thus, the basis of the rejection is not clear.

Rau also fails to disclose "a flexible carrier movable between an unstressed state and a deflected and stressed state and including a first end portion that carries the first tissue stimulation element, a second end portion that carries the second tissue stimulation element" as recited in claim 34. It is alleged that the "suction cup" described by Rau is "a flexible carrier movable between an unstressed and a deflected and stressed state" as recited in claim 34. Office Action (p. 5, lines 1-3, 6-8). As shown in Figs. 1a-c, the suction cup 2 only has one needle point 1. The Office Action also refers to Figs. 4 and 5, but these figures show needles 1a-d that extend through the central portion of the suction cup 2. *See*, Rau (Fig. 4). The Office Action has not explained how needles that extend through a central portion of the suction cup correspond to "a flexible carrier movable between an unstressed state and a deflected and stressed state and including a *first end portion* that carries the first tissue stimulation element, a *second end portion* that carries the second tissue stimulation element" as recited in claim 34.

Additionally, as conceded in the Office Action, Rau fails to disclose "a curved interior portion located between the first and second end portions and configured such that the curved interior portion will be in spaced relation to the tissue surface when the end portions are in contact with the tissue surface and the carrier is in the unstressed state" and "a tissue engagement device carried by the curved interior portion of the carrier between the first and second tissue stimulation elements and configured to secure the carrier to the tissue surface in the deflected and stressed state" as recited in claim 34. Office Action (p. 5, lines 19-22).

Rau further fails to disclose "wherein the carrier is configured to press the first tissue stimulation element and the second tissue stimulation element against the tissue surface when in the deflected and stressed state without the first tissue stimulation element and the second tissue stimulation element piercing the tissue" as recited in claim 34. Rather, as discussed above in Section II, it is alleged that the "needle electrode having a pointed tip 1" is a "stimulation electrode" as recited in claim 34, but Rau explains that this needle point 1 is introduced through the physiological 'skin' barrier, and that the needle point 1 has as its essential part one or more short needle points which penetrate into the uppermost largely cast-off cell layers of the horny skin...Rau (Abstract) (emphasis added). Rau (col. 2, lines 42-44) (emphasis added). This is in contrast to pure surface electrodes that are merely brought in contact with the body surface. Rau (Abstract). Accordingly, Rau describes a configuration that is the opposite of the configuration recited in claim 34 since claim 34 specifically recites that the stimulation element does not pierce tissue and in this regard, is a "surface" electrode, which is specifically distinguished by Rau. Rau (Abstract) (distinguishing non-penetrating surface electrodes). In this regard, Rau also teaches away from claim 34.

Franchi and Daddona do not cure these deficiencies such that Rau, Franchi and Daddona, individually and even if somehow combined, fail to disclose each limitation of claim 32.

Franchi is cited for the limited purpose of allegedly disclosing: 1. a flexible carrier having "a curved interior portion" and 2. a tissue engagement device that is carried by the curved interior portion of the carrier between first and second stimulation elements and configured to secure the carrier to the tissue surface in the deflected and stressed state. Office Action (p. 5). The Office Action cites Figs. 6-9 of Franchi, but these figures do not show stimulation electrodes. Further, Applicant notes that claim 34 recites that the flexible carrier is configured

such that there is a curved interior portion between first and second end portions (which carry respective first and second stimulation electrodes), and that this curved interior portion is in spaced relation to the tissue surface when the end portions (which carry respective first and second stimulation electrodes) are in contact with the tissue surface and the carrier is in an unstressed state and, in addition, that a tissue engagement device is carried by the curved interior portion, between the first and second stimulation elements. Figs. 6-9, however, show claws 9 at the ends of the sheet 4. More particularly, Franchi explains that claws are distributed "around the periphery of the sheet 4" or, in other words, on an outer edge of the sheet 4. Franchi (col. 4, lines 17-18) (emphasis added). Thus, Franchi describes a configuration that is the opposite of the configuration recited in claim 34 since the cited claws 9 are positioned around a periphery, or outside of, alleged stimulation elements. Thus, in addition to these deficiencies, Franchi also teaches away from claim 34.

Daddona is cited for the very limited purpose of allegedly disclosing a structure for securing a device to cardiac tissue. Office Action (p. 6). Daddona, however, does not cure the substantial deficiencies discussed above.

Applicant respectfully submits that independent claim 34 is patentable over Rau, Franchi and Daddona, individually and even if somehow combined as alleged. Dependent claims 35-37, 40 and 42 depend from and incorporate the elements of independent claim 34 and, therefore, are also believed patentable over the cited references.

Accordingly, Applicant respectfully request that the rejection of claims 34-37, 40 and 42 under 35 U.S.C. §103(a) be withdrawn.

V. Claim 41 Is Patentable Over Rau, Franchi, Daddona and Baker

Dependent claim 41 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over four references: Rau, Franchi, Daddona and Baker, all of which have been discussed above. Dependent claim 41 incorporates the limitations of independent claim 34 and, therefore is also believed patentable over the cited references in view of the deficiencies discussed above.

Accordingly, Applicant respectfully request that the rejection of claim 41 under 35 U.S.C. §103(a) be withdrawn.

VI. New Claims Are Patentable Over the Cited References

New dependent claims 44-50 depend from and incorporate the limitations of respective independent claims 32-34 and, therefore, are believed patentable over the cited references in view of the above remarks. Various references are also deficient relative to various dependent claims.

For example, claim 44 recites *inter alia* "wherein the *stimulation element does not have a sharpened end*" and claim 49 recites *inter alia* "wherein the first stimulation element and the second stimulation element *do not have sharpened ends*." In contrast, it is alleged that a needle point 1 described by Rau is a "stimulation element"). By its nature, a needle point 1 has a pointed or sharpened end. Thus, Rau describes a configuration that is the opposite of claim 44 and teaches away from claim 44. Further, Hess describes an electrode 21 and tip 37 (collectively alleged to be a "stimulation element"), but Hess explains that the tip 37 is "highly sharpened" and designed to pierce tissue. Thus, Hess describes a configuration that is the opposite of claim 44 and teaches away from claim 44.

Remarks relating to cited references failing to disclose one or two stimulation elements not being configured to pierce tissue apply to claim 45, which recites *inter alia* "wherein the means for securing the surgical apparatus to the tissue structure is configured to pierce a single side of the tissue structure and to press the stimulation element against the single side of the tissue structure_*without the tissue stimulation element piercing the tissue*", claim 47, which recites inter alia "the anchor being configured to pierce the tissue and to press the first stimulation element and the second stimulation element against the tissue *without the first stimulation element and the second tissue stimulation element piercing the tissue*" and claim 50, which recites *inter alia* "wherein the flexible carrier is configured to pierce the tissue and press the first stimulation element and the second stimulation element against the tissue *without the first tissue stimulation element and the second stimulation element piercing the tissue*."

Claim 46, which depends from claim 33, recites *inter alia* "a second tissue stimulation element carried by the anchor, the second tissue stimulation element having a diameter of about 0.5mm to 1.0mm and being configured to emit stimulation energy that is applied to tissue, wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion." Claim 33 stands rejected based on Hess and Baker. Hess, for example, fails to describe

first and second stimulation elements as recited in claim 46 and instead describes a highly sharpened tip 37. Similar remarks apply to claims 47 and 48, which also depend from claim 33.

Claim 50, which depends from claim 34, recites *inter alia* "wherein the flexible carrier is configured to pierce the tissue and press the first stimulation element and the second stimulation element against the tissue without the first tissue stimulation element and the second stimulation element piercing the tissue." Claim 34 stands rejected based on Rau, Franchi and Daddona. Rau, for example, fails to describe first and second stimulation elements as recited in claim 50 and instead describes needle point 50.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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